



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#2!  
L. Simon  
12/18/96

IN RE: Dermatological Composition

APPLICATION NUMBER: 08/154.562

FILED: November 19, 1993

EXAMINER: Samuel Barts

ART UNIT: 1204

DEC 18 1996  
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Dear Mr. Barts:

Following is a response to your Office Action dated October 30, 1996:

Examiner introduces objection under 35 U.S.C.103 based on obviousness. According to examiner, he cites Fourman, et al. U.S. 4,963,591, as his basis.

The legal question of obviousness of a patent can only be resolved after resolving factual issues as to what is the scope and content of prior art; what is the difference between prior art and the claims at issue; and what is the level of ordinary skill in the art, and secondary conditions such as commercial success, long felt but unresolved needs and failure of others to solve problems should be considered if they are present. Mobil Oil Corp. -vs- Amoco Chemical Corp., D. Del. 1991, 779 F. Supp. 1429

In determining obviousness, one must consider the invention as a whole; small differences between the claims and the prior art can give rise to

patentability. Becton Dickinson & Co. -vs- C.R. Bard, Inc. D.N.J. 1989, 719 F Supp. 1228.

Analysis of the level of ordinary skill in the art for determination of obviousness of patent should incorporate types of problems in the art, prior art solutions to the problems, rapidity of innovations in the field, sophistication of the technology, education of the inventor, and the educational level of active workers in the field. Solarex Corp. v Arco Solar, Inc. D. Del. 1992, 805 F. Supp. 252.

In the instant invention, the inventor introduces the  $C_{12}-C_{15}$  ester mixture of Fumaric acid which gives a solid product melting at body temperature.

$C_{12}-C_{15}$  alcohol mixtures are the starting raw materials for a myriad of cosmetic products.  $C_{12}-C_{15}$  alcohol mixtures are an article of commerce.  $C_{12}-C_{15}$  alcohol mixtures are readily available. Further, as a result of this availability, these alcohol mixtures are accepted throughout the cosmetic industry, are readily available and therefore are more economical .

The inventor has been working with this alcohol blend for many years and is a recognized authority in this field of chemistry. Various ester products used in cosmetic formulations use  $C_{12}-C_{15}$  alcohols as their starting ingredients, e.g.:

$C_{12}-C_{15}$  Lactate named Ceraphyl 41 by ISP, Corp.

$C_{12}-C_{15}$  Benzoate by Finetex, Inc.

$C_{12}-C_{15}$  Octanoate called Hetester FAO marketed by the inventor with Bernel Chemical Company.

Also marketed by the inventor is another ester of maleic acid which is

the di-capryl maleate which is the maleic acid ester of di-2-methyl-heptyl alcohol and its isomer the di-2-methyl-heptyl fumarate. These are sold as Bernel Ester DOM and are liquids at body temperature.

Bernel Chemical Company also markets the di-2-ethyl-hexyl fumarate, a liquid at body temperature, sold as Bernel Ester 284. For many years the solid product, which melts at body temperature and is used as an emollient in cosmetic formulations, has been myristyl myristate, trade name, Ceraphyl 424 by ISP, Corp. It suffers from the drawbacks of questionable safety at high concentrations, and sometimes unsatisfactory emolliency. The inventor has been a cosmetic chemist for 39 years and has been issued 12 patents, 7 with his current employer, Bernel Chemical Company. Other than the aforementioned myristyl myristate, there has never been an ester he has invented which has been used as an emollient in cosmetic formulations melting at body temperature.

In the inventor's search for product excellence and safety, he is always concerned with the correlation of chemical structure to the properties of any compound being investigated.

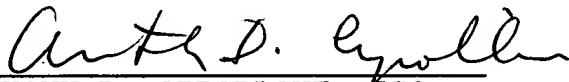
During the inventor's work with maleates, he observed that heating a maleate ester causes the maleate to transform into its trans isomer, the fumarate ester. Once the fumarate is formed, it does not revert to the maleate. The transformation is irreversible. For example, Bernel Chemical Company is marketing dioctylmaleate which is distilled by adjusting the heat, Bernel controls the transformation of the maleate ester into its trans isomer, dioctyl fumarate. Further, if the maleate ester is heated at a high temperature for an extended period of time, it will all transform to fumarate esters.

Since the inventor markets maleic acid derivatives such as dioctyl maleate which is a liquid at body temperature, his inquisitiveness led him to start with fumaric acid alone and reacted this acid with  $C_{12}$ - $C_{15}$  alcohols. To his surprise, the fumarate esters formed were solid at body temperature and exhibited all of the good properties of myristyl myristate and none of its shortcomings. These "new" fumarate ester thickened creams above body temperature, imparted a special feel at body temperature and had excellent safety.

This is the point of the invention, the unique, hitherto unforeseen property that these  $C_{12}$ - $C_{15}$  fumarate esters melt at body temperature. This is a boon to cosmetic chemists everywhere. That is why this is a patentable discovery.

The inventor strongly feels, in view of case law and his explanation, he has overcome examiner's obviousness objection and respectfully requests that Lettres Patent be issued.

Respectfully submitted,



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